

## **REMARKS**

### **I. Status of the Claims and Formal Matters**

With entry of this amendment, claims 1-12 are pending.

Applicant has cancelled claims 13-18 without surrender of the subject matter recited therein.

Applicant has amended claims 1, 5, and 10-12. The amendments do not add new matter.

### **II. The Claims Are Not Indefinite**

The Office rejects claims 1-18 for alleged indefiniteness under 35 U.S.C. § 112, second paragraph. Office Action, p. 2. According to the Office, “[t]he phrase Rb1, Rb2, Rb3, Rb5 Rc, Rd, Re, and Rf in claims 1, 13, 17, and 18; and *Panax* species in claim 5 are enclosed in parenthesis,” and thus it is “unclear if the phrase is a positive limitation to the cited claims.” *Id.* To overcome this rejection, Applicant has amended claims 1 and 5 to delete the parentheses and canceled claims 13-18. Additionally, Applicant has amended claim 5 to delete phrases that preceded the parentheticals.

The Office further asserts that “[t]he term ‘it’ in claim 1, line 4; claim 10, line 3; claim 11, line 3; and claim 12, line 3 is vague because it is unclear to what the term refers. *Id.* To provide clarification, Applicant has amended claims 1, 10, 11, and 12, substituting the word “it” with the term “the mixture of vinegar and ginseng.”

Finally, the Office alleges that, in claim 11, “[i]t is not clear if applicant’s temperature range lower than 90°C, or lower than 70°C, or between 70°C to 90°C.” *Id.* at 3. Applicant has amended claim 11 to correct the minor typographical error by

deleting the phrase “lower than.” Claim 11 now recites “a temperature 70°C to 90°C,” thus providing a clear temperature range.

Applicant respectfully submits that the amended claims apprise the skilled artisan of their scope, and are not indefinite. See M.P.E.P. § 2173.02. Applicant requests that the Office withdraw the indefiniteness rejection.

### **III. The Claims Are Not Obvious**

The Office rejects claims 1-10 and 12-18 as allegedly obvious under 35 U.S.C. § 103(a) over Japanese Patent No. JP 403083565 A, Abstract (“Ogawa”) in view of Korean Patent No. KR 2001047790 A, Abstract (“Choi”) and Korean Patent No. KR 100228510, machine translation (“Kang”) and further evidenced by *Barrett*, “Chemistry in Your Environment” 1994 (“Barrett”). Office Action, p. 4. The Office asserts that Ogawa “discloses a method of making . . . ‘ginseng preparation’ comprising alcohol-extracted concentrated ginseng extract and vinegar and allowed to stand for a fixed period of time.” *Id.* The Office concedes that Ogawa does not teach the step of heating the ginseng-vinegar mixture and that it is “silent regarding the ginseng extract with ginsenosides; amount of ginsenoside Rg3 to total ginsenosides and the pH vinegar as cited.” *Id.*

The Office contends, however, that Kang “discloses a process to obtain a ginseng extract comprising ginsenosides (Abstract) by extraction with organic solvent including alcohol” and “teaches heat exposure and time of ginseng plant in high temperature of 110°C to 180°C for 0.5 hours to 20 hours to increase the content of ginsenoside components in ginseng extract.” *Id.* According to the Office, it “would have

been obvious to one of ordinary skill in the art to use heating parameters of ginseng to produce ginseng extract with increased inherent ginsenoside components as taught by Kang et al. in the process of Ogawa.” *Id.* at 4-5.

With respect to Choi, the Office asserts that it “discloses a method of making a functional vinegar composition comprising extracts of ginseng and white vinegar” and “discloses ginseng in volume of 30% in the vinegar composition.” *Id.* at 5. The Office contends it would have been obvious “to use the amount of Choi’s ginseng extract in Ogawa’s process of making ginseng extract and vinegar composition.” *Id.* Moreover, according to the Office, “[i]t would have been obvious to combine Kang’s process of extraction ginseng extract and Choi’s amount of ginseng extract into Ogawa’s process.” *Id.*

Applicant respectfully traverses. Applicant submits that the Office has not met its burden to show that the claimed methods are *prima facie* obvious. “The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious.” M.P.E.P. § 2142. The Office bears the burden of supplying such a reason. *See id.*

The present invention provides unexpected benefits not contemplated by any of the prior art methods of the invention. The Examiner has identified two “cold” methods for preparing a ginseng-vinegar preparation. As the Office acknowledges, neither Ogawa nor Choi teaches to heat the ginseng-vinegar mixture to obtain a preparation with high ginsenoside content. The vinegar in these preparations was ineffective to extract the desired effective ingredients. As discussed in the present specification, if the

ginseng and vinegar mixture is heated at a temperature below 70°C, a very small amount of effective ingredient is obtained from the final product. Specification, page 9, lines 3-4. Certainly, if it was not heated at all, as in Ogawa or Choi, either only a small amount or no amount of the effective ingredients would be obtained. The vinegar preparations of Ogawa and Choi were not designed to extract specific saponins from ginseng, nor did they accomplish this purpose.

The Examiner relies on Kang for the teaching of heat. However, as for Kang, it does not teach nor suggest the use of vinegar. As pointed out in paragraph [0012] of the present application, Kang teaches that ginseng's effective ingredients, such as Rg<sub>3</sub>, can be obtained when ginseng is treated with a diluted mineral acid (*e.g.*, hydrochloric acid, nitric acid, or perchloric acid) or a low grade organic acid (*e.g.*, acetic, tartaric, or oxalic acid), while being subjected to a high temperature. See Kang, p. 6.

Nothing in Kang would have led to the claimed use of vinegar. In fact, a person of ordinary skill in the art would have recognized that when acids are used to prepare ginseng compositions, the resultant saponin content may be relatively low. For example, the use of citric acid (Comparative Example 2-1 of the present application) or glacial acetic acid (Comparative Example 2-2) results in low ginsenoside content, as demonstrated in Table 2 of the present application. The level of desired Rg<sub>3</sub> from a heated vinegar extraction is 1.93% and 1.27% according to two different embodiments of the invention. In contrast, the use of citric acid resulted in only 0.26% and glacial acetic acid resulted in only 0.59%. See Specification, pages 20-21. This suggests that at least certain acids or certain pH ranges, *e.g.*, citric acid and glacial acetic acid,

prevent generation of Rg<sub>3</sub>. Therefore, it would not have been obvious to one of skill in the art to use yet another acidic substance, such as vinegar, to make a ginseng preparation with high ginsenoside concentration, arriving at the present invention. In fact, it is quite striking that using an acid pH lower than the range of the invention and using an acidic pH that is higher than the range of the invention both are ineffective at producing the desired concentrations of Rg<sub>3</sub>.

Additionally, the Office has failed to account for the deficiencies of Kang. The mineral acids (such as hydrochloric, nitric, or perchloric) and organic acids (such as acetic, tartaric, or oxalic) of Kang are not proper for ingestion and must be removed prior to administration to a subject. Specification, page 5, lines 8-11. The present invention is able to overcome those deficiencies by using a specific vinegar extract at a desired pH, and using a particular heat extraction step. The present invention avoids the additional step of removing the deleterious solvents of Kang. Omission of an element and retention of its function is a reliable indicia of nonobviousness. See MPEP 2144.04(II)(B); *In re Edge*, 359 F.2d 896 (C.C.P.A. 1966). Applicant thus submits that, at least for the reasons articulated above, pending claims 1-12 are not obvious.

With respect to claim 11, the Office cites an additional reference, Korean Patent No. KR 2001055013 A ("Ahn"), stating that it "discloses a sterilizing step by heating the ginseng vinegar at 60°C to 80°C" and that it "would have been obvious to one of ordinary skill in the art to use Ahn's heating step in Ogawa's process of making ginseng/vinegar composition." Office Action, p. 7. Applicant submits, however, that Ahn merely teaches a method for making ginseng vinegar that is sterile; it is not

concerned with its ginsenoside content. In fact, the vinegar-ginseng sterilizing treatment of Ahn is for only 2 to 20 minutes and is presumably to kill the fermenting bacteria that produced the vinegar. In contrast, the heat treatment of the present invention takes from 30 minutes to 24 hours. The rejection of claim 11 has failed to account for all of the limitations of this claim.

In the absence of a reason why the skilled artisan would have arrived at the methods recited in pending claims 1-12, the claims are nonobvious. Applicant requests that the Office withdraw the rejection.

**IV. Conclusion**

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

If there is any fee due in connection with the filing of this paper, please charge the fee to Deposit Account No. 06-0916.

Respectfully submitted,

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